

**TITLE 9. HEALTH SERVICES
CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSURE
ARTICLE 10. OUTPATIENT TREATMENT CENTERS
PROVIDING DIALYSIS SERVICES**

Section

- R9-10-1001. Definitions**
- R9-10-1002. Supplemental Application Requirements; Change of Information**
- R9-10-1003. Administration**
- R9-10-1004. Contracted Services**
- R9-10-1005. Quality Management Program**
- R9-10-1006. Clinical Staff Members**
- R9-10-1007. Non-Clinical Staff Members**
- R9-10-1008. Patient Rights**
- R9-10-1009. Medical Records**
- R9-10-1010. Medication**
- R9-10-1011. Discharge**
- R9-10-1012. Dialysis Services**
- R9-10-1013. Ancillary Services**
- R9-10-1014. Infection Control**
- R9-10-1015. Environmental Services and Equipment Standards**
- R9-10-1016. Medical Emergency, Safety, and Disaster Standards**
- R9-10-1017. Physical Plant Standards**

**ARTICLE 10. OUTPATIENT TREATMENT CENTERS
PROVIDING DIALYSIS SERVICES**

R9-10-1001. Definitions

In addition to the definitions in A.R.S. § 36-401 and 9 A.A.C. 10, Article 1, the following definitions apply in this Article:

1. "Administrator" has the same meaning "chief administrative officer" as defined in R9-10-101.
2. "Admission" means an individual, after the completion of the individual's registration, begins receiving dialysis services at an outpatient treatment center providing dialysis services and is accepted as a patient of the outpatient treatment center providing dialysis services.
3. "Adverse reaction" means an unexpected outcome that threatens the health and safety of a patient as a result of medical services provided to the patient.
4. "Ancillary services" means those medical services performed to assist in assessing or determining the cause of a medical condition.
5. "Assessment" means an analysis of a patient's need for dialysis services.
6. "Authenticate" means to establish authorship of a document or an entry in a medical record by:
 - a. A written signature;
 - b. An individual's initials, if the individual's written signature appears on the document or in the medical record;
 - c. A rubber-stamp signature; or
 - d. An electronic signature code.
7. "Available" means:
 - a. For an individual, the ability to be contacted by any means possible such as by telephone or pager;
 - b. For equipment and supplies, retrievable at an outpatient treatment center providing dialysis services; and
 - c. For a document, retrievable in writing or electronically at an outpatient treatment center providing dialysis services or accessible according to the time-frames in this Article.
8. "Biohazardous medical waste" has the same meaning as in A.A.C. R18-13-1401.
9. "Biological" means a medicinal compound prepared from living organisms and their products such as a serum, vaccine, antigen, or antitoxin.
10. "Caregiver" means an individual designated by a patient or a patient's representative to perform self-dialysis in the patient's stead.
11. "Chief clinical officer" means an individual who is responsible for the direction of medical services provided to a patient.
12. "Clean" means to remove dirt or debris by methods such as washing with soap and water, vacuuming,

wiping, dusting, or sweeping.

13. "Clinical laboratory services" means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the prevention, diagnosis, or treatment of a disease or impairment of a human being, including procedures to determine, measure, or describe the presence or absence of substances or organisms in the human body.
14. "Clinical privilege" means authorization to provide medical services granted by a governing authority to a medical staff member.
15. "Clinical staff member" means an individual granted clinical privileges or a compensated individual or volunteer who works for or at an outpatient treatment center providing dialysis services who is:
 - a. One of the individuals defined as a health professional in A.R.S. § 32-3201, excluding a veterinarian licensed under A.R.S. Title 32, Chapter 21;
 - b. A hemodialysis technician defined in A.R.S. § 36-423; or
 - c. A medical assistant defined in A.R.S. §§ 32-1401, 32-1501, 32-1800, and 32-2901.
16. "Compensated" means receives payment in exchange for services provided to an outpatient treatment center providing dialysis services.
17. "Conspicuously posted" means displayed in the area where the public enters the premises of an outpatient treatment center providing dialysis services.
18. "Consultation" means evaluation and advice about a patient's treatment by an individual upon request of a clinical staff member or a non-clinical staff member.
19. "Contracted services" means dialysis services or environmental services provided at an outpatient treatment center providing dialysis services according to a written agreement between the outpatient treatment center providing dialysis services and a person who provides the dialysis services or environmental services.
20. "Controlled substance" has the same meaning as in A.R.S. § 36-2501.
21. "Credit hour" means one earned academic unit of study based on attending a one hour class session per calendar week.
22. "Current" means up-to-date and extending to the present time.
23. "Diagnostic procedure" means a method or process performed to determine whether an individual has a medical condition.
24. "Dialysis" means the process to remove dissolved substances from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.
25. "Dialysis services" means medical services, nursing services, and health-related services provided to a patient receiving dialysis.
26. "Dialyzer" means a filter used in hemodialysis to remove wastes and excess fluid from a patient's blood.

DRAFT- 02/07/07

27. *"Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.*
28. "Disaster" means an unexpected event, such as a fire, flood, extreme weather, or bomb threat that affects an outpatient treatment center's ability to provide dialysis services.
29. "Discharge" means a documented termination of dialysis services to a patient by an outpatient treatment center providing dialysis services.
30. "Disinfect" means to clean to prevent the growth of or destroy disease-carrying microorganisms.
31. "Documentation" or "documented" means information in written, photographic, electronic, or other permanent form.
32. "Drill" means a response to a planned, simulated event.
33. "Drug" has the same meaning as in A.R.S. § 32-1901.
34. "Electronic" has the same meaning as in A.R.S. § 44-7002.
35. "Electronic signature" has the same meaning as in A.R.S. § 44-7002.
36. "Environmental services" means activities such as housekeeping, laundry, and facility and equipment maintenance.
37. "Equivalent" means credit hours in subjects typically taught at the college or university level, which are equal to or in excess of the number of credit hours typically required to obtain a bachelor's degree.
38. "Exploitation" has the same meaning as in A.R.S. § 46-451.
39. "Health care directive" has the same meaning as in A.R.S. § 36-3201.
40. "Hemodialysis" means the process for removing wastes and excess fluids from a patient's blood by passing blood through a dialyzer.
41. "Hospital" has the same meaning as in R9-10-201.
42. "Hour" means 60 clock minutes.
43. "Incident" means an unexpected occurrence that results in patient death, or that harms or has the potential to harm a patient while the patient is on an outpatient treatment center's premises or receiving dialysis services from the outpatient treatment center providing dialysis services.
44. "Informed consent" means advising a patient of a proposed treatment or diagnostic procedure, alternatives to the treatment or diagnostic procedure, associated risks, and possible complications, and obtaining permission from the patient or the patient's representative for the treatment or diagnostic procedure.
45. "Inservice education" means organized instruction or information related to dialysis services provided to a clinical staff member or non-clinical staff member.
46. "Isolation" means the separation, during the communicable period, of infected individuals or animals from others, to limit the transmission of infectious agents.
47. "License" means the documented authorization:

DRAFT- 02/07/07

- a. Issued by the Department to operate an outpatient treatment center providing dialysis services, or
 - b. Issued to an individual to practice a profession in this state.
48. "Long-term care plan" means a written plan of action for a patient with kidney failure that:
- a. Is developed to achieve long-term optimum patient outcome, and
 - b. Meets the requirements of R9-10-1012(E).
49. "Medical condition" means the state of a patient's physical or mental health, including the patient's illness, injury, or disease.
50. "Medical emergency" means a potentially life-threatening occurrence that requires an immediate response or treatment.
51. "Medical history" means an account, based on the information provided by a patient, of the patient's past and present medical condition related to the reason the patient is receiving dialysis services.
52. "Medical record" has the same meaning as "medical records" in A.R.S. § 12-2291.
53. "Medical staff member" means a physician, a physician assistant, or a registered nurse practitioner.
54. "Medication" has the same meaning as drug.
55. "Medication error" means:
- a. The failure to administer a medication as ordered, or
 - b. The administration of a medication not ordered.
56. "Modality" means a method of treatment for kidney failure, including transplant, hemodialysis, and peritoneal dialysis.
57. "Monitor" means to check systematically on a specific condition or situation.
58. "Nephrologist" means a physician who is board eligible or board certified in nephrology by a professional credentialing board.
59. "Nephrology" means the subspecialty of medicine that deals with conditions and diseases that affect the kidneys.
60. "Non-clinical staff member" means a volunteer or compensated individual, other than a clinical staff member, who works for or at an outpatient treatment center providing dialysis services.
61. "Nurse" means a registered nurse or a practical nurse.
62. "Nutritional assessment" means an analysis of a patient's weight, height, lifestyle, medication, mobility, food and fluid intake, and diagnostic procedures to identify conditions and behaviors that indicate that the patient's nutritional needs are not being met.
63. "Order" means an instruction by a medical staff member to provide dialysis services to a patient.
64. "Orientation" means the initial instruction and information provided to an individual starting work or volunteer services in or for an outpatient treatment center providing dialysis services.
65. "Patient" means an individual admitted to receive dialysis services.

DRAFT- 02/07/07

66. "Patient care plan" means a written document for a patient receiving dialysis that:
 - a. Is developed to meet the patient's needs for medical services, nursing services, and health-related services; and
 - b. Meets the requirements of R9-10-1012(F).
67. "Patient follow-up instructions" means information relevant to a patient's medical condition that is provided to the patient, the patient's representative, or a health care institution.
68. "Patient's representative" means a patient's legal guardian, an individual acting on behalf of a patient with the written consent of the patient, or a surrogate as defined to A.R.S. § 36-3201.
69. "Peritoneal dialysis" means the process of using the peritoneal cavity for removing waste products by fluid exchange.
70. "Person" has the same meaning as in A.R.S. § 1-215 and includes governmental agencies.
71. "Pharmaceutical services" means those activities pertaining to the compounding, distribution, and dispensing of drugs, devices, and chemicals.
72. "Physical examination" means to observe, test, or inspect an individual's body to evaluate health or determine cause of illness, injury, or disease.
73. "Physician" has the same meaning as in A.R.S. § 36-401.
74. "Physician assistant" means an individual licensed under A.R.S. Title 32, Chapter 25.
75. "Practical nurse" has the same meaning as in A.R.S. § 32-1601.
76. "Professional credentialing board" means a non-governmental organization that designates individuals who have met or exceed established standards for experience and competency in a specific field.
77. "Psychosocial evaluation" means an analysis of an individual's mental and social conditions to determine the individual's need for social work services.
78. "Quality management program" means activities designed and implemented by an outpatient treatment center providing dialysis services to improve the delivery of dialysis services.
79. "Registered dietitian" means an individual approved to work as a dietitian by the American Dietetic Association's Commission on Dietetic Registration.
80. "Registered nurse" has the same meaning as in A.R.S. § 32-1601.
81. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.
82. "Registration" means a documented determination by an outpatient treatment center providing dialysis services that an individual is eligible to receive dialysis services from the outpatient treatment center providing dialysis services.
83. "Reprocessing" means cleaning and sterilizing a dialyzer previously used by a patient so that it can be reused by the same patient.
84. "Restraint" means any chemical or physical method of restricting a patient's freedom of movement,

DRAFT- 02/07/07

physical activity, or access to the patient's own body.

- 85. "Risk" means potential for an adverse outcome.
- 86. "Scope of dialysis services" means a list of specific medical services, nursing services, and health-related services the governing authority of an outpatient treatment center providing dialysis services has designated as being available to a patient.
- 87. "Seclusion" means the involuntary solitary confinement of a patient in a room or an area where the patient is prevented from leaving.
- 88. "Self-dialysis" means dialysis performed by a patient or a caregiver on the patient's body.
- 89. "Shift" means the beginning and ending time of a staff work period.
- 90. "Signature" means:
 - a. The first and last name of an individual written with his or her own hand as a form of identification or authorization, or
 - b. An electronic signature.
- 91. "Social worker" means an individual licensed under A.R.S. Title 32, Chapter 33, Article 5.
- 92. "Social work services" has the same meaning as "practice of social work" in A.R.S. § 32-3251.
- 93. "Stable" means a patient's blood pressure, temperature, pulse, respirations, and diagnostic procedures results are within medically recognized acceptable ranges so that medical intervention is not indicated.
- 94. "Student" means an individual attending an educational institution through an arrangement between the outpatient treatment center providing dialysis services and the educational institution.
- 95. "Transplant surgeon" means a physician who:
 - a. Is board eligible or board certified in general surgery or urology by a professional credentialing board, and
 - b. Has at least 12 months of training or experience performing renal transplants and providing care for patients with renal transplants.
- 96. "Treatment" means a procedure or method to cure, improve, or palliate a medical condition.
- 97. "Vascular access" means the point on a patient's body where bloodlines are connected for hemodialysis.
- 98. "Verification" means:
 - a. A documented telephone call including the date and the name of the documenting individual,
 - b. A documented observation including the date and the name of the documenting individual, or
 - c. A documented confirmation of a fact including the date and the name of the documenting individual.
- 99. "Volunteer" means an individual authorized by an outpatient treatment center providing dialysis services to work without compensation for the outpatient treatment center providing dialysis services.

R9-10-1002. Supplemental Application Requirements; Change of Information

DRAFT- 02/07/07

- A. In addition to the license application requirements in A.R.S. §§ 36-422 and 36-424 and 9 A.A.C. 10, Article 1, a governing authority applying for an initial or renewal license shall submit a supplemental application form provided by the Department that contains the:
 - 1. Days and hours of clinical operation and, if different than the days and hours of clinical operation, the days and hours of administrative operation;
 - 2. Name of the chief clinical officer; and
 - 3. Types and number of clinical staff members and non-clinical staff members who will be providing dialysis services for or at the outpatient treatment center providing dialysis services.
- B. A governing authority shall ensure the Department is notified:
 - 1. According to A.R.S. § 36-422(D) for termination of operations or a change of ownership;
 - 2. According to A.R.S. § 36-425(E) for a change in an administrator; and
 - 3. In writing, no later than ten business days after the date of a change in the information required in subsection (A)(1) or (A)(2).

R9-10-1003. Administration

- A. If an outpatient treatment center providing dialysis services is operating under a single group license issued to a hospital according to A.R.S. § 36-422 (F) and (G), the hospital's governing authority is the governing authority for the outpatient treatment center providing dialysis services.
- B. A governing authority shall:
 - 1. Consist of one or more individuals with overall authority and responsibility for an outpatient treatment center providing dialysis services;
 - 2. Establish, in writing, the scope of dialysis services to be provided by or at the outpatient treatment center providing dialysis services;
 - 3. Approve and sign all policies and procedures for the outpatient treatment center providing dialysis services;
 - 4. Require all policies and procedures be reviewed at least once every three years and updated as needed;
 - 5. Approve or designate an individual to approve contracted services;
 - 6. Adopt a quality management program that complies with R9-10-1005;
 - 7. Review and evaluate the effectiveness of the quality management program in R9-10-1005 at least once every 12 months; and
 - 8. Ensure compliance with federal and state laws, rules, and local ordinances applicable to outpatient treatment center providing dialysis services.
- C. A governing authority shall appoint in writing:
 - 1. An administrator who meets one of the following:

DRAFT- 02/07/07

- a. Is a registered nurse who has at least 12 months experience in an outpatient treatment center providing dialysis services,
 - b. Has a baccalaureate degree and at least 12 months experience in an outpatient treatment center providing dialysis services, or
 - c. Has at least 24 months of experience as an administrator in an outpatient treatment center providing dialysis services before the effective date of these rules;
 2. An acting administrator, if an administrator is expected to be unavailable for more than 30 consecutive days; and
 3. A chief clinical officer who is a physician to direct the medical services provided by or at the outpatient treatment center providing dialysis services who:
 - a. Is board eligible or board certified in internal medicine or pediatrics by a professional credentialing board, and
 - b. Has at least 12 months of experience or training in providing dialysis services.
- D. Under the direction of the governing authority of the outpatient treatment center providing dialysis services, an administrator shall:
1. Implement the governing authority's direction for the operations of the outpatient treatment center providing dialysis services;
 2. Act as a liaison between the governing authority, clinical staff members, and non-clinical staff members;
 3. Designate, in writing, an individual by name or title who is available to implement the operations of the outpatient treatment center providing dialysis services when the administrator is not available for a period of less than 30 consecutive days;
 4. Comply with:
 - a. Tuberculosis reporting requirements in A.A.C. R9-6-202, and
 - b. Tuberculosis control requirements in A.A.C. R9-6-373;
 5. For infectious tuberculosis screening:
 - a. Ensure that each clinical staff member, non-clinical staff member, volunteer, or student submits:
 - i. On or before the starting date of employment or volunteer service, one of the following as evidence of freedom from infectious pulmonary tuberculosis:
 - (1) Documentation of a negative Mantoux skin test or other tuberculosis screening test recommended by the U.S. Centers for Disease Control and Prevention administered within six months before the starting date of employment or volunteer service that includes the date and the type of

- tuberculosis screening test; or
- (2) If the staff member or volunteer has had a positive Mantoux skin test or other tuberculosis screening test, a written statement that the staff member or volunteer is free from infectious pulmonary tuberculosis signed by a physician, physician assistant, or registered nurse practitioner dated within six months before the starting date of employment or volunteer service; and
- ii. Every 12 months after the anniversary date of employment or volunteer, one of the following as evidence of freedom from infectious pulmonary tuberculosis:
 - (1) Documentation of a negative Mantoux skin test or other tuberculosis screening test recommended by the U.S. Centers for Disease Control and Prevention administered before or within 30 days after the anniversary date of the most recent tuberculosis screening test or written statement that includes the date and the type of tuberculosis screening test; or
 - (2) If the staff member or volunteer has had a positive Mantoux skin test or other tuberculosis screening test, a written statement that the staff member or volunteer is free from infectious pulmonary tuberculosis signed by a physician, physician assistant, or registered nurse practitioner dated before or within 30 days after the anniversary date of the most recent tuberculosis screening test or written statement; or
- b. Establish, document, and implement a tuberculosis infection control program that complies with the Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings, 2005 published by the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30333 available at <http://www.cdc.gov/mmwr/PDF/rr/rr5417.pdf>, incorporated by reference, on file with the Department, and including no future editions and amendments and includes:
 - i. Conducting tuberculosis risk assessments, conducting tuberculosis screening testing, screening for signs or symptoms of tuberculosis, and providing training and education related to recognizing the signs and symptoms of tuberculosis; and
 - ii. Maintaining documentation of any:
 - (1) Tuberculosis risk assessment;
 - (2) Tuberculosis screening test of a clinical staff member, non-clinical staff member, volunteer, or student; or
 - (3) Screening for signs or symptoms of tuberculosis of a clinical staff member,

non-clinical staff member, volunteer, or student; and

6. Ensure that:
 - a. A minimum of one registered nurse or medical staff member is on the premises at all times while a patient is on the premises;
 - b. A medical staff member is available at all times during hours of operation;
 - c. A work schedule containing each clinical staff member's and non-clinical staff member's schedule is:
 - i. Planned, reviewed, adjusted, dated, and documented;
 - ii. Maintained for at least 24 months from the date of the work schedule; and
 - iii. Provided to the Department within two hours after the Department's request;
 - d. Job descriptions, job qualifications, and job responsibilities for each type of clinical staff member and non-clinical staff member are written;
 - e. A record is maintained for each student providing services at the outpatient treatment center providing dialysis services for 24 months after the last date the student provides services that contains:
 - i. The student's name, address, and starting date;
 - ii. Documentation of the student's compliance with the tuberculosis control requirements in subsection (D)(5); and
 - iii. A description of the services the student is able to provide at the outpatient treatment center providing dialysis services;
 - f. Policies and procedures are established, documented, and implemented that cover:
 - i. Scope of dialysis services and how dialysis services are provided;
 - ii. Inservice education that ensures that a clinical staff member or a non-clinical staff member continues to be qualified to provide the dialysis services in the clinical staff member's or non-clinical staff member's job description;
 - iii. Health care directives;
 - iv. A method of patient identification to ensure the patient receives the dialysis services ordered;
 - v. Long-term care plans and patient care plans;
 - vi. Clinical staff members' response to a patient's adverse reaction during dialysis;
 - vii. Clinical staff members' response to an equipment malfunction during dialysis;
 - viii. Patient admission and discharge;
 - ix. Patient follow-up instructions;
 - x. Assessment and reassessment of patients;

- xi. Medical records including oral, telephone, and electronic records;
 - xii. The use of electronic signatures;
 - xiii. Basic adult and pediatric cardiopulmonary resuscitation training requirements and renewal of training, including method and content of training, qualifications of individual providing the training, the time-frame for renewal of training, and the documentation that verifies a clinical staff member has received the training;
 - xiv. Obtaining informed consent;
 - xv. Dispensation, administration, and disposal of medications and biologicals;
 - xvi. Students providing services at the outpatient treatment services providing dialysis services;
 - xvii. Waste management;
 - xviii. Disaster plans;
 - xix. Use of restraint and seclusion; and
 - xx. Complaints including the process by which a clinical staff member or a non-clinical staff member may submit a complaint related to patient care to the outpatient treatment center providing dialysis services;
- g. The policies and procedures are available to each clinical staff member and non-clinical staff member;
- h. The following are conspicuously posted:
 - i. The current license for the outpatient treatment center providing dialysis services issued by the Department;
 - ii. The name, address, and telephone number of the Department;
 - iii. A notice that a patient may file a complaint with the Department about the outpatient treatment center providing dialysis services;
 - iv. A schedule of rates according to A.R.S. § 36-436.01(C);
 - v. A list of patient rights;
 - vi. A map for evacuating the facility; and
 - vii. A notice identifying the location on the premises where current license inspection reports required in A.R.S. § 36-425(D), with patient information redacted, are available; and
- i. Patient follow-up instructions are:
 - i. Provided, orally or in written form, to a patient or the patient's representative before the patient leaves the outpatient treatment center providing dialysis services unless the patient leaves against a clinical staff member's advice;

- ii. If a patient returns to a health care institution, provided orally or in written form, when the patient returns to the health care institution, to the registered nurse responsible for the nursing services provided to the patient at the health care institution or to the individual responsible for the medical services, nursing services, or health-related services provided to the patient at the health care institution; and
- iii. Documented in the patient's record.

R9-10-1004. Contracted Services

An administrator shall ensure that:

- 1. A contractor provides contracted services according to the requirements in this Article;
- 2. A contract specifies the responsibilities of the contractor and the outpatient treatment center providing dialysis services; and
- 3. An outpatient treatment center providing dialysis services:
 - a. Maintains a copy of each contract;
 - b. Maintains a list of current contracted services on the premises; and
 - c. Provides to the Department, within two hours after the Department's request, a contract copy required in subsection (3)(a) or a list required in subsection (3)(b).

R9-10-1005. Quality Management Program

- A. A governing authority shall ensure that an outpatient treatment center providing dialysis services has an ongoing quality management program.
- B. An administrator shall ensure that:
 - 1. A written plan for a quality management program for an outpatient treatment center providing dialysis services is established, documented, and implemented that includes:
 - a. A method to identify, document, and evaluate incidents;
 - b. A method to collect data to evaluate the delivery of dialysis services;
 - c. A method to evaluate the data collected to identify a concern about the delivery of dialysis services;
 - d. A method to make changes or take action as a result of the identification of a concern about the delivery of dialysis services;
 - e. A method to determine whether actions taken improved the delivery of dialysis services; and
 - f. The frequency of submitting the documented report required in subsection (B)(2);
 - 2. A documented report is submitted to the governing authority that includes:
 - a. Each identified concern in subsection (B)(1)(c), and

DRAFT- 02/07/07

- b. Any change made or action taken in subsection (B)(1)(d); and
- 3. The report in subsection (B)(2) and the supporting documentation is:
 - a. Maintained for 24 months from the date the report is submitted to the governing authority, and
 - b. Provided to the Department within two hours after the Department's request.

R9-10-1006. Clinical Staff Members

- A. An administrator shall ensure that:
 - 1. Clinical staff members are available to provide all the dialysis services included in the scope of dialysis services required in R9-10-1003(B)(2);
 - 2. A clinical staff member's skills to provide dialysis services are verified and documented upon employment or volunteer service and every 12 months from the date of employment or volunteer service;
 - 3. A clinical staff member:
 - a. Only provides dialysis services the clinical staff member is qualified to provide;
 - b. Completes basic cardiopulmonary resuscitation training specific to the age of the patient receiving dialysis services from the outpatient treatment center:
 - i. Before providing dialysis services, and
 - ii. At least once every 24 months after the initial date of employment or volunteer services;
 - c. Complies with the requirements in A.R.S. § 36-423 and R9-10-112 for hemodialysis technicians and hemodialysis technician trainees, if applicable; and
 - d. Wears a name badge that displays the individual's first name, job title, and professional license or certification;
 - 4. Orientation is provided to each clinical staff member, beginning the first week of employment, that covers:
 - a. Specific job responsibilities of the clinical staff member;
 - b. Policies and procedures;
 - c. Patient rights;
 - d. Disaster plans;
 - e. Infection control requirements including:
 - i. Handwashing;
 - ii. Prevention of communicable diseases; and
 - iii. If applicable, linen handling;
 - f. Department rules for licensing and regulating outpatient treatment centers providing

- dialysis services and how the rules may be obtained; and
- g. The process by which a clinical staff member may submit a complaint about patient care to an outpatient treatment center providing dialysis services;
- 5. For each clinical staff member a record is maintained that includes:
 - a. The clinical staff member's resume or application;
 - b. Documentation of the clinical staff member's starting date of employment or volunteer service;
 - c. Verification or documentation of the clinical staff member's certification, licensure, or education, as applicable;
 - d. Documentation of granting of clinical privileges, if applicable;
 - e. Documentation of completion of cardiopulmonary resuscitation training required in subsection (A)(3)(b);
 - f. Documentation of the clinical staff member's compliance with the infectious tuberculosis screening requirements in R9-10-1003(D)(5); and
 - g. Documentation of completion of orientation required in subsection (A)(4);
- 6. The record in subsection (A)(5) is maintained for at least 24 months after the last date the clinical staff member provides dialysis services;
- 7. Each clinical staff member completes at least eight hours of inservice education every 12 months from the starting date of employment or volunteer service;
- 8. Inservice education required in subsection (A)(7) is documented and the documentation includes:
 - a. The date of completion of the inservice education,
 - b. The subject matter and description of the inservice education,
 - c. The number of inservice education hours provided by the inservice education, and
 - d. The signature of the clinical staff member certifying completion of the inservice education; and
- 9. A clinical staff member's record required in subsection (A)(5) or inservice education documentation required in subsection (A)(8) is provided to the Department within two hours after the Department's request.
- B. If an outpatient treatment center providing dialysis services uses a clinical staff member contracted through an employment agency, an administrator shall ensure that the contract requires the employment agency to:
 - 1. Maintain the documentation required in subsection (A)(5) for each clinical staff member employed by the employment agency for at least 24 months from the date the clinical staff member last provides services for or at the outpatient treatment center providing dialysis services; and
 - 2. Provide the documentation required in subsection (B)(1) within two hours after a request by the

DRAFT- 02/07/07

outpatient treatment center providing dialysis services or the Department.

R9-10-1007. Non-Clinical Staff Members

A. An administrator shall ensure that:

1. Non-clinical staff members are available to provide all the dialysis services included in the scope of dialysis services required in R9-10-1003(B)(2);
2. A non-clinical staff member only provides dialysis services the non-clinical staff member is qualified to provide;
3. Orientation is provided to each non-clinical staff member, beginning the first week of employment that covers:
 - a. Specific job responsibilities of the non-clinical staff member;
 - b. Policies and procedures;
 - c. Patient rights;
 - d. Disaster plans;
 - e. Infection control requirements including:
 - i. Handwashing;
 - ii. Prevention of communicable diseases; and
 - iii. If applicable, linen handling;
 - f. Department rules for licensing and regulating outpatient treatment centers providing dialysis services and how the rules may be obtained; and
 - g. The process by which a non-clinical staff member may submit a complaint about patient care to an outpatient treatment center providing dialysis services;
4. For each non-clinical staff member a record is maintained that includes:
 - a. The non-clinical staff member's resume or application;
 - b. The non-clinical staff member's starting date of employment or volunteer service;
 - c. If applicable to the non-clinical staff member's job position, verification or documentation of certification, licensure, or education;
 - d. Evidence of the non-clinical staff member's compliance with the infectious tuberculosis screening requirements in R9-10-1003(D)(5); and
 - e. Documentation of the non-clinical staff member's orientation required in (A)(4);
5. The record in subsection (A)(4) is maintained for at least 24 months after the last date of the non-clinical staff member's employment or volunteer service at the outpatient treatment center providing dialysis services;
6. Each non-clinical staff member who provides dialysis services to patients completes 8 hours of inservice education every 12 months from the starting date of employment or volunteer service;

DRAFT- 02/07/07

7. Inservice education required in subsection (A)(6) is documented and the documentation includes:
 - a. The date of completion of the inservice education,
 - b. The subject matter and description of the inservice education,
 - c. The number of inservice education hours provided by the inservice education, and
 - d. The signature of the non-clinical staff member certifying completion of the inservice education, and
 8. A non-clinical staff member's record required in subsection (A)(5) or inservice education documentation required in subsection (A)(7) is provided to the Department within two hours after the Department's request.
- B. If an outpatient treatment center providing dialysis services uses a non-clinical staff member contracted through an employment agency, an administrator shall ensure that the contract requires the employment agency to:
1. Maintain the documentation required in subsection (A)(5) for each non-clinical staff member employed by the employment agency for at least 24 months from the date the non-clinical staff member last provided services at the outpatient treatment center providing dialysis services; and
 2. Provide the documentation obtained in subsection (B)(1) within two hours after a request by the outpatient treatment center providing dialysis services or the Department.

R9-10-1008. Patient Rights

An administrator shall ensure that:

1. A patient is:
 - a. Is provided privacy in treatment and personal care needs; and
 - b. Free from:
 - i. The intentional infliction of physical, mental, or emotional harm when not medically indicated;
 - ii. Exploitation;
 - iii. Restraint and seclusion when not medically indicated unless necessary to prevent harm to self or others and the reason for restraint and seclusion is documented in the patient's medical record;
 - iv. Sexual abuse according to A.R.S. § 13-1404; and
 - v. Sexual assault according to A.R.S. § 13-1406;
2. A patient or the patient's representative:
 - a. Consents to treatment or a diagnostic procedure before the treatment or diagnostic procedure is initiated, except in a medical emergency;
 - b. Is allowed to refuse an examination or withdraw consent for treatment or a diagnostic

- procedure before an examination, treatment, or diagnostic procedure is initiated; and
- c. Except in a medical emergency, receives the following:
 - i. Information about the outpatient treatment center's policies and procedures for health care directives;
 - ii. Information about the outpatient treatment center's complaint policies and procedures, including the telephone number of an individual at the outpatient treatment center providing dialysis services to contact about a complaint and the Department's telephone number; and
 - iii. Information about proposed treatments or diagnostic procedures, alternatives to treatments or diagnostic procedures, associated risks, and possible complications; and
- 3. A consent obtained from a patient or the patient's representative and information provided to the patient or the patient's representative are documented in the patient's medical record.

R9-10-1009. Medical Records

- A. An administrator shall ensure that:
 - 1. A medical record for each patient is established and maintained according to A.R.S. § 12-2297;
 - 2. A medical record is available to a clinical staff member or non-clinical staff member authorized by the outpatient treatment center's policies and procedures to access the medical record;
 - 3. Information in a medical record is only disclosed to a third party with the written authorization of the patient or the patient's representative or as permitted or required by law;
 - 4. A medical record is provided to the Department within two hours after a request by the Department;
 - 5. A medical record is protected from loss, damage, or unauthorized use or disclosure;
 - 6. An entry in a medical record:
 - a. Is recorded only by an individual authorized by the outpatient treatment center's policies and procedures to make the entry;
 - b. Is legible, dated, and authenticated; and
 - c. Remains legible when a correction to the original entry is made;
 - 7. In addition to the entry requirements in subsection (A)(6), each order is:
 - a. Dated when the order is entered in the medical record including the time of the order; and
 - b. Authenticated by a medical staff member according to the outpatient treatment center's policies and procedures, if the order is entered by an individual who is not a medical staff member;
 - 8. If a rubber-stamp signature, electronic signature, or electronic code is used to authenticate an order,

DRAFT- 02/07/07

the medical staff member to whom the rubber-stamp signature, electronic signature, or electronic code belongs is responsible for the use of the rubber stamp, electronic signature, or electronic code;

9. A verbal order is entered and authenticated according to the requirements in subsection (A)(7); and
10. If the outpatient treatment center providing dialysis services ceases operations, the Department is notified in writing, not less than 30 days before operations cease, of the location where the medical records are stored.

B. If an outpatient treatment center providing dialysis services maintains medical records electronically, an administrator shall ensure that:

1. There are safeguards to prevent unauthorized access, and
2. An internal clock records the date and time of a medical record entry.

C. An administrator shall ensure that a medical record for each patient contains:

1. Documented informed consent for treatment or a diagnostic procedure by the patient or the patient's representative except in a medical emergency;
2. A diagnosis or reason for dialysis services;
3. A medical history and physical examination performed as required in R9-10-1012(A)(1), R9-10-1012(A)(2), and R9-10-1012(A)(3);
4. Patient information that includes:
 - a. The patient's name and address;
 - b. The patient's date of birth;
 - c. If applicable, the name of a designated patient representative; and
 - d. Any known allergy or sensitivity;
5. Medication information that includes:
 - a. A medication or biological ordered for the patient;
 - b. A medication or biological administered to the patient including:
 - i. The date and time of administration;
 - ii. The name, strength, dosage, amount, vaccine lot number if applicable, and route of administration;
 - iii. The identification and authentication of the individual administering the medication or biological; and
 - iv. Any adverse reaction a patient has to the medication or biological; and
 - c. A prepackaged or sample medication provided to the patient for self-administration including the name, strength, dosage, amount, and route of administration;
6. The name of each individual providing treatment or a diagnostic procedure to the patient;
7. Documentation of each order;

DRAFT- 02/07/07

8. Documentation of each clinical laboratory test result and radiological and diagnostic imaging report required in R9-10-1013, if applicable;
9. Documentation of each dialysis service provided to the patient;
10. If applicable, documentation of self-dialysis required in R9-10-1012(B)(5);
11. Notes by a clinical staff member or non-clinical staff member, including the patient's response to a treatment or diagnostic procedure;
12. Monthly notes related to the patient's progress by a medical staff member, registered dietitian, social worker, and registered nurse;
13. If a health care directive is provided by the patient or the patient's representative, a copy of the health care directive signed by the patient or the patient's representative;
14. Documentation of the patient instructions to the patient;
15. Documentation of the patient's discharge including the disposition of the patient upon discharge; and
16. If applicable, a consultation report.

R9-10-1010. Medication

An administrator shall ensure that:

1. If pharmaceutical services that require a pharmacy license are provided on the premises:
 - a. The pharmaceutical services comply with A.R.S. Title 36, Chapter 27; A.R.S. Title 32, Chapter 18; and 4 A.A.C. 23; and
 - b. A copy of the pharmacy license is provided to the Department upon request;
2. A medication or a biological:
 - a. Is maintained at the temperature recommended by the manufacturer of the medication or biological;
 - b. Is administered in compliance with an order; and
 - c. Administered to a patient, is documented as required in R9-10-1010(C)(5);
3. A drug reference source, current within one year of the publication date, is available and maintained on the premises for use by clinical staff members;
4. Policies and procedures are established, documented, and implemented for:
 - a. Receiving, inventorying, tracking, dispensing, and discarding prepackaged and sample medication including expired medication;
 - b. Discarding or returning prepackaged and sample medication to the manufacturer if the manufacturer requests the discard or return of the medication;
 - c. A medication recall and notification of patients who received recalled medication;
 - d. Storing, inventorying, and dispensing controlled substances; and

DRAFT- 02/07/07

- e. Documenting the maintenance of a medication or biological requiring refrigeration; and
5. A medication error or an adverse reaction is reported to the ordering medical staff member and documented in the patient's medical record.

R9-10-1011. Discharge

An administrator shall ensure that after a patient's discharge from an outpatient treatment center providing dialysis services, the nephrologist responsible for the dialysis services provided to the patient documents the patient's discharge in the patient's medical record within 30 days after the patient's discharge and includes:

1. A description of the patient's medical condition and the dialysis services provided to the patient, and
2. The signature of the nephrologist.

R9-10-1012. Dialysis Services

A. An administrator of an outpatient treatment center providing dialysis services shall ensure that:

1. The dialysis services provided to a patient meet the needs of the patient;
2. A physician performs a medical history and physical examination on a patient within 30 days before admission or with 48 hours after admission and documents the medical history and physical examination in the patient's medical record within 48 hours after admission;
3. If the patient's medical history and physical examination required in subsection (1) is not performed by the patient's nephrologist, the patient's nephrologist, within 30 days of the date of the medical history and physical examination:
 - a. Reviews and authenticates the patient's medical history and physical examination, documents concurrence with the medical history and physical examination, and includes information specific to nephrology, or
 - b. Performs a medical history and physical examination that includes information specific to nephrology;
4. A patient's nephrologist or the nephrologist's designee:
 - a. Performs a medical history and physical examination on the patient at least once every 12 months from the date of the patient's admission to the outpatient treatment center providing dialysis services, and
 - b. Documents monthly notes related to the patient's progress in the patient's medical record;
5. A registered nurse responsible for the nursing services provided to a patient receiving dialysis services:
 - a. Reviews with the patient, the results of any diagnostic tests performed on the patient;
 - b. Assesses the patient's medical condition before the patient begins receiving hemodialysis and after the patient has received hemodialysis;

- c. If the patient returns to a health care institution after receiving dialysis services, provides an oral or written notice of information related to the patient's medical condition to the registered nurse responsible for the nursing services provided to the patient at the health care institution or if there is not a registered nurse responsible, the person responsible for the medical services, nursing services, or health-related services provided to the patient at the health care institution;
 - d. Inform the patient's nephrologist of any changes in a patient's medical condition or needs; and
 - e. Documents in the patient's medical record:
 - i. Any notice provided as required in subsection (A)(5)(c); and
 - ii Monthly notes related to the patient's progress;
- 6. Before dialysis is provided to a patient who is not stable, a nephrologist is notified of the patient's medical condition and dialysis is not provided until the nephrologist provides direction;
- 7. A patient receiving dialysis services:
 - a. Is under the care of a nephrologist;
 - b. Is assigned a patient identification number according to the policy and procedure in R9-10-1003(D)(4)(g)(iv);
 - c. Is identified by a clinical staff member before beginning dialysis;
 - d. Receives the dialysis services ordered for the patient by a medical staff member;
 - e. Is monitored by a clinical staff member while receiving dialysis at least once every 30 minutes; and
 - f. If the outpatient treatment center providing dialysis services reprocesses and reuses dialyzers, is informed that the outpatient treatment center providing dialysis services reprocesses and reuses dialyzers before beginning hemodialysis;
- 8. Supplies and equipment used for dialysis services are used, stored, and discarded according to manufacturer's recommendations;
- 9. If hemodialysis is provided to a patient, a clinical staff member:
 - a. Inspects the dialyzer before use to ensure that the:
 - i. External surface of the dialyzer is clean;
 - ii. Dialyzer label is intact and legible;
 - iii. Dialyzer, blood port, and dialysate port are free from leaks and cracks or other structural damage; and
 - iv. Dialyzer is free of visible blood and other foreign material;
 - b. Verifies the order for the dialyzer to ensure the correct dialyzer is used for the correct

- patient;
 - c. Verifies the duration of dialyzer storage based on the type of germicide used or method of sterilization or disinfection used;
 - d. Verifies that the label on the dialyzer includes:
 - i. The patient's name and the patient's identification number,
 - ii. The number of times the dialyzer has been used in patient treatments,
 - iii. The date of the last use of the dialyzer by the patient, and
 - iv. The date of the last reprocessing of the dialyzer;
 - e. If the patient's name is similar to the name of another patient receiving dialysis in the same facility, informs other clinical staff members and non-clinical staff members of the similar name to ensure that the name or other identifying information on the label corresponds to the correct patient; and
 - f. Ensures that a patient's vascular access is visible to a clinical staff member at all times during dialysis;
- 10. Each patient receiving dialysis is visible to a nurse at a location used by nurses to coordinate patients and treatment;
 - 11. If a patient has an adverse reaction during dialysis, a medical staff member and a clinical staff member respond by implementing the policy and procedure required in R9-10-1003(D)(6)(f)(vi); and
 - 12. If the equipment used during dialysis malfunctions, a medical staff member and a clinical staff member respond by implementing the policy and procedure required in R9-10-1003(D)(6)(f)(vii).
- B. If an outpatient treatment center providing dialysis services provides support for self-dialysis services, an administrator shall ensure that:
- 1. A patient or the patient's caregiver is:
 - a. Instructed to use the equipment to perform self-dialysis by a clinical staff member trained to provide the instruction, and
 - b. Monitored in the patient's home to assess the patient's or patient caregiver's ability to use the equipment to perform self-dialysis;
 - 2. Instruction provided to a patient as required in subsection (B)(1) and monitoring in the patient's home as required in (B)(2) is documented in the patient's medical record;
 - 3. All supplies for self-dialysis necessary to meet the needs of the patient are provided to the patient;
 - 4. All equipment for self-dialysis necessary to meet the needs of the patient is provided for the patient and maintained by the outpatient treatment center providing dialysis services according to the manufacturer's recommendations;

DRAFT- 02/07/07

5. The water used for hemodialysis is tested and treated according to the requirements in subsection (H);
6. Documentation of the self-dialysis maintained by the patient or the patient's caregiver is:
 - a. Reviewed to ensure that the patient is receiving continuity of care, and
 - b. Placed in the patient's medical record; and
7. If a patient uses self dialysis and self-administers medication or a biological:
 - a. The medical staff member responsible for the dialysis services provided to the patient reviews the patient's diagnostic laboratory tests;
 - b. The patient and the patient's caregiver are informed of any potential:
 - i. Side effects of the medication or biological; and
 - ii. Hazard to a child having access to the medication or biological and, if applicable, a syringe used to inject the medication or biological; and
 - c. The patient or the patient's caregiver is:
 - i. Taught the route and technique of administration and is able to administer the medication or biological, including injecting the medication or biological;
 - ii. Taught and able to perform sterile techniques if the patient or the patient's caregiver will be injecting the medication or biological;
 - iii. Provided with instructions for the administration of the medication or biological including the specific route and technique the patient or the patient's caregiver has been taught to use;
 - iv. Able to read and understand the medication or biological label;
 - v. Taught and able to self-monitor the patient's blood pressure; and
 - vi. Informed how to store the medication or biological according to the manufacturer's instructions.
- C. An administrator shall ensure that a social worker is employed by or contracted with an outpatient treatment center providing dialysis services to meet a patient's need including:
 1. Conducting an initial psychosocial evaluation of the patient within 30 days of the patient's admission to the outpatient treatment center providing dialysis services,
 2. Participating in reviewing the patient's need for social work services,
 3. Recommending changes in treatment based on the patient's psychosocial evaluation,
 4. Assisting the patient and the patient's representative in obtaining and understanding information for making decisions about the medical services provided to the patient,
 5. Identifying community agencies and resources and assisting the patient and the patient's representative to utilize the community agencies and resources,

DRAFT- 02/07/07

6. Documenting monthly notes related to the patient's progress in the patient's medical record, and
 7. Conducting a follow-up psychosocial evaluation of the patient at least once every 12 months from the date of the patient's admission to the outpatient treatment center providing dialysis services.
- D. An administrator shall ensure that a registered dietitian is employed by or contracted with an outpatient treatment center providing dialysis services to meet a patient's nutritional and dietetic needs including:
1. Conducting an initial nutritional assessment of the patient within 30 days of the patient's admission to the outpatient treatment center providing dialysis services,
 2. Consulting with the patient's nephrologist and recommending a diet to meet the patient's nutritional needs,
 3. Providing advice to the patient and the patient's representative regarding a diet prescribed by the patient's nephrologist,
 4. Monitoring the patient's adherence and response to a prescribed diet,
 5. Reviewing with the patient any diagnostic test performed on the patient that is related to the patient's nutritional or dietetic needs;
 6. Documenting monthly notes related to the patient's progress in the patient's medical record, and
 7. Conducting a follow-up nutritional assessment of the patient at least once every 12 months from the date of the patient's admission to the outpatient treatment center providing dialysis services.
- E. An administrator shall ensure that a long-term care plan for each patient:
1. Is developed by a team that includes at least:
 - a. The chief clinical officer of the outpatient treatment center providing dialysis services;
 - b. If the chief clinical officer is not a nephrologist, the patient's nephrologist;
 - c. A transplant surgeon or the transplant surgeon's designee;
 - d. A registered nurse responsible for nursing services provided to the patient;
 - e. A social worker;
 - f. A registered dietitian; and
 - g. The patient or patient's representative, if the patient or patient's representative chooses to participate in the development of the long-term care plan;
 2. Identifies the modality of treatment and dialysis services to be provided to the patient;
 3. Is reviewed and approved by the chief clinical officer;
 4. Is signed and dated by each clinical staff member and non-clinical staff member participating in the development of the long-term care plan;
 5. Includes documentation signed by the patient or the patient's representative that the patient or the patient's representative was provided an opportunity to participate in the development of the long-term care plan;

DRAFT- 02/07/07

6. Is signed and dated by the patient or the patient's representative; and
 7. Is reviewed at least every 12 months by the team in subsection (E)(1) and updated according to the patient's needs.
- F. An administrator shall ensure that a patient care plan for each patient:
1. Is developed by a team that includes at least:
 - a. The patient's nephrologist;
 - b. A registered nurse responsible for nursing services provided to the patient;
 - c. A social worker;
 - d. A registered dietitian; and
 - e. The patient or the patient's representative, if the patient or patient's representative chooses to participate in the development of the patient care plan;
 2. Includes an assessment of the patient's need for dialysis services;
 3. Identifies treatment and treatment goals;
 4. Is signed and dated by each clinical staff member and non-clinical staff member participating in the development of the patient care plan;
 5. Includes documentation signed by the patient or the patient's representative that the patient or the patient's representative was provided an opportunity to participate in the development of the patient care plan;
 6. Is signed and dated by the patient or the patient's representative;
 7. Is implemented;
 8. Is evaluated by:
 - a. The registered nurse responsible for the dialysis services provided to the patient;
 - b. The registered dietitian responsible for the dialysis services provided to the patient related to the patient's nutritional or dietetic needs; and
 - c. The social worker responsible for the dialysis services provided to the patient related to the patient's psychosocial needs;
 9. Includes documentation of interventions, resolutions, and outcomes related to treatment goals; and
 10. Is reviewed and updated according to the needs of the patient:
 - a. At least every 6 months for a patient whose medical condition is stable, and
 - b. At least every 30 days for a patient who medical condition is not stable;
- G. If an outpatient treatment center providing dialysis services reuses dialyzers or other dialysis supplies, an administrator shall ensure that the outpatient treatment center providing dialysis services conforms to the guidelines adopted by the Association for the Advancement of Medical Instrumentation in "Reuse of hemodialyzers, ANSI/AAMI RD47:2002 & RD47:2002/A1:2003," incorporated by reference, on file with

DRAFT- 02/07/07

the Department, and including no future editions or amendments. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.

- H. An administrator shall ensure that the quality of water used in dialysis conforms to the guidelines adopted by the Association for the Advancement of Medical Instrumentation in "Hemodialysis systems, ANSI/AAMI RD5:2003," incorporated by reference, on file with the Department, and including no future editions or amendments. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.

R9-10-1013. Ancillary Services

An administrator shall ensure that:

1. If clinical laboratory services are provided on the premises or by contracted services at another location:
 - a. The clinical laboratory services are provided by a laboratory that holds a certificate of accreditation or certificate of compliance issued by the United States Department of Health and Human Services under the Clinical Laboratory Improvement Act of 1967, 42 U.S.C. 263a, as amended by Public Law 100-578, October 31, 1988; and
 - b. A copy of the certificate of accreditation or certificate of compliance is provided to the Department within two hours after the Department's request;
2. A clinical laboratory test result is documented in a patient's medical record including:
 - a. The name of the clinical laboratory test;
 - b. The patient's name;
 - c. The date of the clinical laboratory test;
 - d. The results of the test; and
 - e. If applicable, any adverse reaction to the test;
3. If radiology services or diagnostic imaging services are provided on the premises or by contracted services at another location:
 - a. The radiology services or diagnostic imaging services are provided in compliance with A.R.S. Title 30, Chapter 4, and 12 A.A.C. 1; and
 - b. A copy of the certificate of compliance is provided to the Department within two hours after the Department's request; and
4. A radiological or diagnostic imaging report is documented in a patient's medical record including:
 - a. The name of the procedure;
 - b. The patient's name;
 - c. The date of the procedure;

- d. If applicable:
 - i. The type and amount of radiopharmaceutical used, and
 - ii. Any adverse reaction to the procedure or radiopharmaceutical; and
- e. An interpretation of the image by a physician, dentist, registered nurse practitioner, or physician's assistant.

R9-10-1014. Infection Control

- A. An administrator shall ensure that:
 - 1. An infection control program is established, documented, and implemented with specific measures to prevent, detect, control, and investigate infections and communicable diseases;
 - 2. Policies and procedures are established, documented, and implemented that cover:
 - a. Compliance with the requirements in 9 A.A.C. 6 for reporting and control measures for communicable diseases and infestations;
 - b. Handling and disposal of biohazardous medical waste according to 18 A.A.C. 13, Article 14;
 - c. Isolation of a patient;
 - d. Sterilization and disinfection of medical equipment and supplies;
 - e. Use of personal protective equipment such as gloves, gowns, masks, or face protection;
 - f. Cleaning an individual's hands when the individual's hands are visibly soiled;
 - g. Housekeeping procedures that ensure a clean environment;
 - h. Training of staff in infection control practices;
 - i. Cleaning soiled linens and clothing; and
 - j. Work restrictions for a clinical staff member or non-clinical staff member with a communicable disease or infected skin lesion;
 - 3. Soiled linen and clothing are:
 - a. Collected in a manner to minimize or prevent contamination,
 - b. Bagged at the site of use, and
 - c. Maintained separate from clean linen and clothing;
 - 4. Clean linen and clothing are stored in a manner to prevent contamination;
 - 5. A clinical staff member or a non-clinical staff member washes his or her hands with soap and water or uses a hand disinfection product before and after each patient contact and after handling soiled linen, soiled clothing, or a potentially infectious material;
 - 6. An outpatient treatment center's infection control program includes:
 - a. A method to identify, document, and analyze infections occurring at the outpatient treatment center providing dialysis services;

DRAFT- 02/07/07

- b. A method to evaluate the analysis of infections in subsection (A)(5)(a) to identify a concern about infection control program at the outpatient treatment center providing dialysis services;
 - c. A method to make changes or take action as a result of the identification of a concern about infection control program at the outpatient treatment center providing dialysis services; and
 - d. The frequency of submitting the documented report required in subsection (A)(6);
- 7. A documented report is submitted to the governing authority that includes:
 - a. Each concern identified as required in subsection (A)(5)(b), and
 - b. Any change made or action taken as required in subsection (A)(5)(c); and
- 8. Documentation of an infection control program including reports of communicable diseases is:
 - a. Maintained for 24 months after the date of the documentation or report; and
 - b. Provided to the Department, within two hours after the Department's request.
- B. An administrator shall comply with contagious disease reporting requirements in A.R.S. § 36-621 and communicable disease reporting requirements in 9 A.A.C. 6, Article 2.

R9-10-1015. Environmental Services and Equipment Standards

An administrator shall ensure that:

- 1. An outpatient treatment center's premises are:
 - a. Cleaned and disinfected according to the outpatient treatment center's policies and procedures to control illness and infection, and
 - b. Free from a condition or situation that may cause an individual to suffer physical injury;
- 2. There is a pest control program to control insects and rodents;
- 3. A tobacco smoke-free environment is maintained on the premises;
- 4. Biohazardous medical wastes are identified, stored, and disposed of according to 18 A.A.C. 13, Article 14;
- 5. A refrigerator used to store a medication or a biological is:
 - a. Maintained in working order, and
 - b. Only used to store medications and biologicals;
- 6. Equipment used at the outpatient treatment center providing dialysis services:
 - a. Is maintained in working condition;
 - b. Used according to the manufacturer's recommendations; and
 - c. If applicable, tested and calibrated at least once every 12 months or according to the manufacturer's recommendations; and
- 7. Documentation of an equipment test, calibration, or repair is:
 - a. Maintained for 24 months after the date of testing, calibration, or repair; and

- b. Provided to the Department, within two hours after the Department's request.

R9-10-1016. Medical Emergency, Safety, and Disaster Standards

- A. An administrator shall ensure that policies and procedures for providing medical emergency treatment are established, documented, and implemented that protect the health and safety of patients and include:
 - 1. The medications, supplies, and equipment required on the premises for the medical emergency treatment provided by the outpatient treatment center providing dialysis services;
 - 2. A system to ensure all medications, supplies, and equipment are available, have not been tampered with, and, if applicable, have not expired; and
 - 3. A cart or a container is available for medical emergency treatment that:
 - a. Contains all of the medication, supplies, and equipment specified in the outpatient treatment center's policies and procedures; and
 - b. Is verified and documented according to the outpatient treatment center's policies and procedures.
- B. An administrator shall ensure that:
 - 1. A disaster plan is developed, documented, and implemented that includes:
 - a. Procedures for protecting the health and safety of patients and other individuals on the premises,
 - b. Assigned responsibilities for each clinical staff member or non-clinical staff member,
 - c. Instructions for the evacuation of patients and other individuals on the premises, and
 - d. Arrangements to provide dialysis services to meet patients' needs;
 - 2. A disaster plan required in subsection (B)(1) is reviewed at least once every 12 months;
 - 3. A fire drill is conducted on each shift at least once every 12 months;
 - 4. A disaster plan review required in subsection (B)(2) or a fire drill required in subsection (B)(4) is documented as follows:
 - a. The date and time of the drill or plan review;
 - b. The name of each clinical staff member and non-clinical staff member participating in the drill or plan review;
 - c. A critique of the drill or plan review; and
 - d. If applicable, recommendations for improvement; and
 - 5. Documentation required in subsection (B)(5) is:
 - a. Maintained for 24 months after the date of the drill or plan review; and
 - b. Provided to the Department, within two hours after the Department's request;
 - 6. A fire evacuation plan is posted and accessible to clinical and non-clinical staff members that includes a floor plan of the outpatient treatment center providing dialysis services facility on which

- lines have been drawn through corridors and exits showing the evacuation path;
7. If the local fire jurisdiction requires illuminated exit signs, the exit signs are illuminated;
 8. A corridor in the outpatient treatment center providing dialysis services is at least 44 inches wide;
 9. Corridors and exits are kept clear of any obstructions;
 10. A patient can exit through any exit during hours of operation;
 11. A smoke detector is installed in the each hallway of the outpatient treatment center providing dialysis services facility;
 12. Each smoke detector required under subsection (B)(9) is:
 - a. Maintained in an operable condition; and
 - b. Either battery operated or, if hard-wired into the electrical system of the outpatient treatment center providing dialysis services facility, has a back-up battery; and
 - c. Tested monthly;
 13. There is a portable, operable fire extinguisher labeled as rated at least 2A-10-BC by the Underwriters Laboratories available at the outpatient treatment center providing dialysis services;
 14. The fire extinguisher required in subsection (B)(14):
 - a. Is serviced at least once every 12 months;
 - b. Has a tag attached to the fire extinguisher that specifies the date of the last servicing and the name of the servicing; and
 - c. Is in a fire extinguisher cabinet or placed on wall brackets so that the top handle of the fire extinguisher is not over five feet from the floor and the bottom of the fire extinguisher is at least four inches from the floor;
 15. If a local fire jurisdiction requires a sprinkler system, a sprinkler system is
 - a. Installed,
 - b. Operable,
 - c. Tested quarterly, and
 - d. Serviced at least once every 12 months;
 16. An extension cord is not used instead of permanent electrical wiring;
 17. Each electrical outlet and electrical switch has a cover plate that is in good repair;
 18. If applicable, a sign is placed at the entrance of a room or an area indicating that oxygen is in use;
 19. Oxygen and medical gas containers:
 - a. Are maintained in a secured, upright position;
 - b. Are stored in a room with a door; and
 - i. In a building with sprinklers, at least 5 feet from any combustible materials; or
 - ii. In a building without sprinklers, at least 20 feet from any combustible materials.

R9-10-1017. Physical Plant Standards

An administrator shall ensure that:

1. An outpatient treatment center providing dialysis services licensed after the effective date of this Section, complies with the physical plant health and safety codes and standards that are incorporated by in A.A.C. R9-1-412 at the time the outpatient treatment center providing dialysis services is licensed;
2. For an outpatient treatment center providing dialysis services licensed after the effective date of this Section, architectural plans and specifications for construction or modification are submitted to the Department for approval;
3. Construction or a modification complies with the requirements of this Article and the physical plant health and safety codes and standards incorporated by reference in A.A.C. R9-1-412 at the time the construction or modification is approved by the Department; and
4. The licensed outpatient treatment center providing dialysis services premises or any part of the licensed premises is not leased to or used by another person during the outpatient treatment center providing dialysis services clinical hours of operation.